



JAW W

PATENT APPLICATION

File No: 02-24

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

: Kevin M. Klucher, Pallavur V. Sivakumar, Wayne R. Kindsvogel,

Katherine E. Henderson

Serial No.

10/691,923

Group Art Unit

1646

Examiner

.

Filed

: October 23, 2003

For

: METHODS FOR TREATING VIRAL INFECTION USING IL-28

AND IL-29

## **CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence, comprising:

- 1. Information Disclosure Statement
- 2. PTO-1449 Form
- 3. 45 References
- 4. Return Postcard

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

on April 22, 2005.

Kim M. Goplen





PATENT APPLICATION

File No: 02-24

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Kevin M. Klucher, Pallavur V. Sivakumar, Wayne R. Kindsvogel,

Katherine E. Henderson

Serial No. : 10/691,923

Group Art Unit : 1646

Examiner

Filed : October 23, 2003

For : METHODS FOR TREATING VIRAL INFECTION USING IL-28

AND IL-29

Date Submitted : April 22, 2005

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the examination of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56. Further, in accordance with 37 CFR 1.98(a)(2)(i), applicants have not enclosed copies of the U.S. patent publications listed on form PTO-1449.

In accordance with 37 C.F.R. 1.97, the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been conducted, nor shall it be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. Applicants believe that their invention as claimed is patentable over the references. It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Applicants also wish to bring the Examiner's attention to U.S. Patent Application Serial No. 09/895,834, filed June 29, 2001, entitled "INTERFERON-LIKE PROTEIN ZCYTO21;" U.S. Patent Application Serial No. 10/127,816, filed April 19, 2002, entitled "CYTOKINE PROTEIN FAMILY;" U.S. Patent Application Serial No. 10/914,772, filed August

9, 2004, entitled "HOMOGENEOUS PREPARATIONS OF IL-28 AND IL-29;" and U.S. Patent Application Serial No. 11/098,662, filed April 4, 2005, entitled "METHODS FOR TREATING VIRAL INFECTION USING IL-28 AND IL-29 CYSTEINE MUTANTS;" a copy of each is provided herewith.

Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event that a fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully submitted,

Brian J. Walsh

Registration No. 45,543

· ()	MAY O	3 8						Sheet 1 of 4		
FORM P	<b>Q14</b> 4	2 marie U.S.	. DEPARTI FENT AND	File No. 02-24		Serial No. 10/691,923				
INFORMATION SISCLOSURE STATEMENT BY APPLICANT  MAN 0 4 2000 several sheets if necessary)						Applicant(s): Kevin M. Klucher, Pallavur V. Sivakumar, Wayne R. Kindsvogel, Katherine E. Henderson				
THE TRACE IS						Filing Date: October 23, 2003		oup: 1646		
. ***	•			U.S. PATENT DOCUMEN	TS					
Examiner Initial	Al	DOCUMENT NUMBER 2003/0104416	DATE 06/05/03	NAME Sheppard et al.	CLASS 435	SUBCLASS 6		FILING DATE IF APPROPRIATE		
	A2 A3 A4	2004/0029228 2002/0039763 2004/0138122	02/12/04 04/04/02 07/15/04	Presnell et al. Sheppard et al. Klucher et al.	435 435 514	69.1 69.1 12				
	A5	5,206,344	04/27/93	Katre et al.	530	351				
			FO	REIGN PATENT DOCUM	ENTS					
EXAMINER INITIAL	1.6	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	S SUBCLASS		FILING DATE IF APPROPRIATE		
	A6 A7	03/066002	08/14/03 10/31/02	WIPO WIPO		-				
	A8	03/089603	10/31/02	WIPO			*			
	A9	02/20569	03/14/02	WIPO	-					
<u> </u>	A10	02/092762	11/21/02	WIPO				•		
	A11	0 032 134	07/15/81	EP						
	A12	04/037995	05/06/04	WIPO						
				(Including Author, Title, D						
	A13	Kotenko et al., "IFN-λs mediate antiviral protection through a distinct class II cytokine receptor complete Nature Immunology 4(1):69-77, 2003.								
	A14	Sheppard et al., "IL-28, Il-29 and their class II cytokine receptor IL-28R," <i>Nature Immunology 4(1)</i> :63-68, 2003.								
	A15	Langer et al., "The Class II cytokine receptor (CRF2) family: overview and patterns of receptor-ligand interactions," Cytokine and Growth Factor Reviews 15:33-48, 2004.								
	A16	Donnelly et al., "The expanded family of class II cytokines that share the IL-10 receptor-2 (IL-10R2) chair Leukocyte Biol. 76:314-321, 2004.								
	A17	Dumoutier et al., "Role of the Interleukin (IL)-28 Receptor Tyrosine Residues for Antiviral and Antiproliferative Activity of IL-29/Interferon-λ1," J. Biochem. 279(31):32269-32274, 2004.								
	A18	Univ	versity Calif. S	Santa Cruz Genome Browser - Chro	mosome 19, A	pril 20, 2001.				
Examiner				Date consid	lered					

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	1 M	Wasin	副	11		Sheet 2 of 4					
FORM PT		0	3/5	DEPARTA	MENT OF COMMERCE	File No. 02	-24	Serial No.			
(REV 2-32)		T& TRADE	PAT	ENT AND	TRADEMARK OFFICE			10/691,923			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  Applicant(s):											
\o\'	<b>5</b> 3					Kevin M. K					
	j) 2000 -	severa	il shee	ets if necess	ary)	Sivakumar,		_			
MAY 0	Y KUUD	<b>2</b>				Katherine E. Henderson					
<b>15</b>	اد	<i>§</i>				Filing Date: Group: 1646					
U.S. PATENT DOCUMENTS											
EXAMINER DOCUMENT FILING DATE IF											
INITIAL		NUMBER		DATE	NAME	CLASS SUBCLASS		APPROPRIATE			
FOREIGN PATENT DOCUMENTS											
EXAMINER INITIAL		DOCUMEN NUMBER	Т	DATE	COUNTRY	CLASS	SURCLASS	FILING DATE IF			
HITTAL	INITIAL NUMBER DATE COUNTRY CLASS SUBCLASS APPROPRIATE										
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Patents, etc.)											
	A19		Unive	ersity Calif. Sa	nta Cruz Genome Browser Databa	se – August 6, 2	001, Accessio	n No. C19001210.			
	A20		University Calif. Santa Cruz Genome Browser Database – August 6, 2001, Accession No. C19001212.								
	A21		University Calif. Santa Cruz Genome Browser Database – August 6, 2001, Accession No. C19001213.								
	A22		University Calif. Santa Cruz Genome Browser Database – December 22, 2001, Accession No. C19001260.								
	ļ										
	A23		Univ	ersity Calif. Sa	nta Cruz Genome Browser Databa	se – December 2	2, 2001, Acce	ession No. C19001256.			
	A24		Univ	ersity Calif. Sa	nta Cruz Genome Browser Databa	se – December 2	2, 2001, Acce	ession No. C19001257.			
	105			110 17		01 1 1 1	A G011445				
	A25	Ensembl Contig. View Sanger Institute – April 19, 2001, Accession No. AC011445.						•			
	A26	Ensembl Contig. View Sanger Institute – April 18, 2000, Accession No. AC018477.									
	A27 Adams et al., "3,400 expressed sequence tags identify diversity of transcripts from human brain," Nat. Genet.										
	A27			6-267, 1993.	b expressed sequence tags identity	diversity of train	scripts from i	uman oram, war. Gener.			
					VID 000000110 C 1 1 1 1 1 1 1	00					
	A28	GenBank Submission XP-002202436, October 12, 2000.									
	A29		GenBank Submission XP-002202437, December 12, 1999.								
	430		17: 1	1 . 1 . 4	Maral Interference 1.22 Co. 1.2	D 11	. d. T.	nto-form Deag-to-27 I			
	A30		Kindsvogel et al., "Novel Interferon-Like Cytokines not Recognized by the Type I Interferon Receptor," J. Interferon Cytokine Res. 22(1):S-48, 2002.								
	A31		Adan	ns et al Acces	sion No. T07139, 1993.						
	, 51										
	A32		DOE	Joint Genome	Institute Stanford Human Genome	e Center, Access	ion No. AC01	1445, 1999.			
	A33 Muzney et al., Accession No. AC007458, 1999.										
Duamin	1 . 20		1.7421	, 0, /1000		and d					
Examiner					Date consid	erea					

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

			U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		File No. 02-24		Serial No. 10/691,923		
INFORMA	TION	DISCLOSURE	E STATEME	Applicant(s): Kevin M. Klucher, Pallavur V.					
	J)	Jse several she	ets if necess	Sivakumar, Wayne R. Kindsvogel,					
	`				Katherine E. Henderson				
				Filing Date: Group: 1646		Group: 1646			
			October 23,	2003					
		<u> </u>	U	ITS					
EXAMINER INITIAL	ĺ	DOCUMENT NUMBER	DATE	Name	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
FOREIGN PATENT DOCUMENTS									
EXAMINER		DOCUMENT	DATE	COUNTRY	CLASS SUBCLASS		FILING DATE IF		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Patents, etc.)									
	A34	Univ	ersity of Calife	ornia Santa Cruz database using So	oftherry Inc. gen	e prediction s	oftware Accession No		
	154		01084, 2001.	Tima Santa Ciuz database using St	ntoeny, me. gen	e prediction s	ortware, recession its.		
	125	5	1 . WTL - D	1 1	1-1		- " Notes Constitut		
	A35	Scott et al., "The Pendred syndrome gene encodes a chloride-iodide transport protein," <i>Nature Genetics</i> , 21:440-443, 1999.							
	A36		Korba et al., "A cell culture assay for compounds which inhibit hepatitis B virus replication," Antiviral Research 15:217-228, 1991.						
	A37	Brack et al., "Molecular analysis of the human interferon-α gene family," Gene 15:379-394, 1981.							
	A38	Francis et al., "PEGylation of cytokines and other therapeutic proteins and peptides: the importance of biological optimization of coupling techniques," <i>International Journal of Hematology</i> , 68(1):1-18, 1998.							
	A39	Rajarathnam et al., "Disulfide Bridges in Interleukin-8 Probed Using Non-Natural Disulfide Analogues: dissociation of Roles in Structure from Function," <i>Biochemistry</i> 38:7653-7658, 1999.							
		dissociation of Roles in Structure from Punction, Diochemistry 30: 1033-1030, 1777.							
	A40	Luxon et al., "Pegylated Interferons for the Treatment of Chronic Hepatitis C Infection," Clinical Therapeutics 24(9):13631383, 2002.							
	A41	Kozlowski et al., "Improvements in protein OEGylation: pegylated interferons for treatment of hepatitis C,"  Journal of Controlled Release 72:217-224, 2001.							
	A42		Goodson et al., "Site-Directed Pegylation of Recombinant Interleukin-2 at its Glycosylation Site," <i>Bio/Technology</i> 8(4):343-346, 1990.						
	A43			ure-Function Studies of Interleuki Iomology Modeling," J. Biochem			genesis, Polyethylene Glycol		
Examiner	•			Date consid					
I .				whether or not citation is in ot considered. Include copy					

		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			File No. 02	2-24	Serial No. 10/691,923				
INFORMA			JRE STATE	Applicant(s): Kevin M. Klucher, Pallavur V. Sivakumar, Wayne R. Kindsvogel, Katherine E. Henderson							
				•	Filing Date: Group: 1646 October 23, 2003		Group: 1646				
				U.S. PATENT	DOCUMEN	TS					
EXAMINER INITIAL			DATE	NAME		CLASS SUBCLASS		FILING DATE IF APPROPRIATE			
			F	OREIGN PATE	NT DOCUM	ENTS					
Examiner Initial		DOCUMENT NUMBER	DATE	COUNTRY		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Patents, etc.)										
	A44	Burge et al., "Prediction of Complete Gene Structures in Human Genomic DNA," J. Mol. Biol. 268:78-94, 1997.									
	A45	Vilcek, "Novel interferons," Nature Immunology 4(1):8-9, 2003.									
	-			•		·					
	<del> </del>										
<u> </u>	<u> </u>										
					-						
T	1				Date consid						
Examiner					Date consid	erea					
				ed, whether or not d not considered.				E.P. 609; Draw line ommunication to			